

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY)	MDL No. 1456
AVERAGE WHOLESALE PRICE)	
LITIGATION)	DECLARATION OF THOMAS A.
)	TEMMERMAN, SR. ASSISTANT
)	ATTORNEY GENERAL, IN
)	SUPPORT OF REPLY BRIEF FILED
)	BY THE STATE OF CALIFORNIA
THIS DOCUMENT RELATES TO:)	TO DISMISS FEDERAL C.M.S.
State of California, <i>et al.</i> v. Abbott Laboratories, <i>et al.</i>))	REBATE FRAUD ALLEGATIONS
CASE NO. 1:03-cv-11226-PBS)	AND REMAND THE CASE TO
)	STATE COURT
)	
)	Date: December 12, 2003
)	Time: 2:00 p.m.
)	Judge: Patti B. Saris
)	

I, THOMAS A. TEMMERMAN, hereby declare and state as follows:

1. I am a Senior Assistant Attorney General assigned to the Bureau of Medi-Cal Fraud and Elder Abuse, Criminal Division, California Department of Justice. At all times since the above-captioned *qui tam* matter was filed I have had overall management and supervision of it on behalf of the California Attorney General. At the present time, Deputies Attorney General William S. Schneider, Timothy Foote, John Fisher, and Dennis Fenwick are all assigned to the active management of this case subject to my supervision and that of Supervising Deputy Attorney General Eliseo Sisneros.

2. In July 1998, the Ven-A-Care relators filed their initial complaint under seal and served it along with their disclosure statement on the California Attorney General. Thereafter, our office commenced our investigation of this matter, as mandated by California and federal law.

The complaint alleged a complicated and sophisticated scheme to defraud California's Medicaid program ("Medi-Cal") through excessive reimbursement of pharmaceutical products. The complaint further alleged that this conduct by the pharmaceutical industry had spanned over a decade and involved thousands of different pharmaceutical products by numerous different pharmaceutical companies.

3. Initially, we utilized our own internal sources to gather together data and other pricing information regarding the subject companies and their pharmaceutical products. Also, we obtained data from the relators. As the Bureau is primarily a criminal prosecution unit, I also assigned a criminal deputy in our office to investigate the documents and information we had obtained to determine if criminal prosecutions might be appropriate. During this time, we obtained court-ordered extensions of the seal to obtain additional time to conduct our various investigations and negotiated a multi-state settlement with one pharmaceutical manufacturer.

4. In October 2000, in furtherance of that investigation, our office issued California specific investigative subpoenas to the Defendants named in the *qui tam* complaint pursuant to California Government Code Section 11181 et. seq.

5. In August 2002, the Relators filed their First Amended Complaint which added more companies than their initial complaint and several times as many pharmaceutical products. The First Amended Complaint also contained allegations of rebate fraud by some but not all of the companies involving the federal Center for Medicare and Medicaid Services (C.M.S.) formerly the Health Care Finance Administration (H.C.F.A.).

6. By January of 2003, our office had acquired sufficient data and information about Defendants Abbott and Wyeth to institute an enforcement action against them. I further

determined that such action should be instituted under California's civil False Claims Act rather than criminal statutes. Accordingly, I instructed Mr. Schneider and our staff to prepare a complaint-in-intervention against Abbott and Wyeth based on California state law only. These two companies are reimbursed for their pharmaceutical products on the basis of Direct Price under California's Code of Regulations as opposed to Average Wholesale Price which is one of the national standards. To my knowledge, California is one of the only states in the Union, if not the only State, whose Medicaid program reimburses on the basis of Direct Price.

7. Furthermore, in the preparation of the Abbott-Wyeth complaint-in-intervention, I instructed my staff to deliberately omit any and all C.M.S. rebate fraud claims because our investigation into rebate fraud is not complete. We are required to investigate allegations of fraud primarily from a criminal standpoint. While it is true that the rebate fraud allegations appeared in the Relator's civil complaint it is not the only basis for our investigation.

8. The California Attorney General's investigative subpoenas in connection with C.M.S. rebate fraud are not linked exclusively to the underlying under-seal complaint in the case before the court. The Attorney General has already agreed to settle the issue with other manufacturers in pending settlements arising from investigations in other jurisdictions and with no relationship to the case before this court. These have included both criminal and civil components. Civil prosecutions for Medicaid fraud are but a small part of the overall duty of the Attorney General. The Attorney General is bound to and does primarily prosecute criminal fraud cases under state statutes pursuant to 42 USC Sec. 1396b(q) and 42CFR1007.7.

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42 U.S.C. §1396b (q) provides in part and with emphasis added:

(q) "State medicaid fraud control unit" defined

For the purposes of this section, the term "State medicaid fraud control unit" means a single identifiable entity of the State government . . . as meeting the following requirements:

- (1) The entity (A) is a unit of the office of the State Attorney General or of another department of State government which **possesses statewide authority to prosecute individuals for criminal violations, . . .**
- (2) The entity is separate and distinct from the single State agency that administers or supervises the administration of the State plan under this subchapter.
- (3) The entity's function is conducting a statewide program for the investigation and prosecution of violations of **all applicable State laws** regarding any and all aspects of fraud in connection with (A) any aspect of the provision of medical assistance and the activities of providers of such assistance under the State plan under this subchapter; . . .

Should facts be found to support such allegations California has its own applicable law the anti-kickback statute, Welfare and Institutions Code Section 14107.2, which is a general intent crime similar to but different from the federal statute 42 U.S.C. Section 1320a-7b(b).

9. Thus, our investigation into rebate fraud is neither complete nor is it necessarily linked to this action only. Our rebate fraud investigation continues and may or may not be filed either as a criminal or civil enforcement action other than that which appeared in the Relator's First Amended Complaint and which was meant to be kept under seal pending our investigation.

10. It is my understanding that on September 18, 2003, this Court indicated that if California were to remove the C.M.S. rebate fraud allegations from the First Amended Complaint entirely by dismissing them without prejudice, the Court would reconsider its ruling and remand the remaining State claims to State Court. Even though California has not brought such allegations a dismissal with prejudice of the relators' allegations could be argued to prevent

California from filing a separate civil case and from joining in civil cases in other jurisdictions based on the C.M.S. rebate fraud allegations at any time should the evidence so warrant.

However, a dismissal without prejudice will permit California to file a separate and distinct action for C.M.S. rebate fraud in some other court, state or federal, as would be appropriate. California needs to retain its right to file or join in some other CMS rebate fraud case if and when this office deems that action to be appropriate to protect and make whole the Medi-Cal program. However, I have directed that any such allegations will be filed in a case or cases separate from rather than amended back into this action should the Court grant California's motion to dismiss them without prejudice and remand the case to State Court.

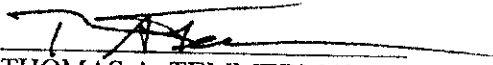
11. At my direction, Deputy Attorney General Schneider sent a letter to Abbott dated September 30, 2003, asking Abbott to preserve Average Manufacturing Price ("A.M.P.") and Best Price ("B.P.") data which pertain to payment of their C.M.S. rebates. The reason for this was that on August 29, 2003, C.M.S. published 68 FR 51912 which was originally scheduled to take effect on October 1, 2003. Under this regulation, pharmaceutical companies were permitted to destroy all such records and data for all but the last three (3) years. The rule, were it to go into effect, would sanction the destruction of all records currently maintained by manufacturers reflecting the A.M.P. and B.P. reports on products paid for by Medicaid agencies, including Medi-Cal, throughout the 1990s.

12. I instructed Mr. Schneider to send the letter not only to Abbott but also to other pharmaceutical companies to preserve and maintain their C.M.S. rebate records and data due to pending investigations by our office. The letter was routine in nature and was not dependent upon, nor connected with, the Ven-A-Care case now pending before this Court.

13. As part of the proposed regulation, C.M.S. invited comments or criticism of the new regulation from the states' attorneys general. Accordingly, on October 28, 2003, the California Attorney General and attorneys general from forty-four (44) other states sent a joint letter to C.M.S. objecting to the proposed regulation insofar as it sets a three-year time limitation on the preservation of C.M.S. rebate data by the pharmaceutical manufacturers. Subsequently, C.M.S. moved back the implementation date for 68 FR 51912 to be implemented to January 1, 2004.

That I have personal knowledge of the foregoing and that this Declaration was executed on November 21, 2003 in Sacramento, California.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

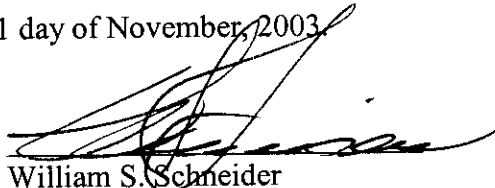

THOMAS A. TEMMERMAN
Sr. Assistant Attorney General

CERTIFICATE OF SERVICE

I hereby certify that I, William S. Schneider, Deputy Attorney General, Bureau of Medi-Cal Fraud and Elder Abuse, for the State of California, caused a true and correct copy of the foregoing:

1. **The State of California's and Relator's Reply Brief in Support of the State of California's and Relator's Notice of Election to Dismiss Rebate Claims from the Case and Amended Memorandum of Law in Support of Motion to Remand Pursuant to the Court's Ruling of September 18 2003,**
2. **Declaration of Thomas A. Temmerman, Sr. Assistant Attorney General In Support of Reply Brief Filed By The State of California to Dismiss Federal C.M.S. Rebate Fraud Allegations and Remand The Case To State Court;**

to be served electronically on counsel of record on the Master Service List, pursuant to Section E of the Case Management Order No. 2, this 21 day of November, 2003.



William S. Schneider
Deputy Attorney General
Bureau of Medi-Cal Fraud and Elder Abuse
State of California